NEAL P. DUNN, MD
2ND DISTRICT, FLORIDA

COMMITTEE ON AGRICULTURE

COMMITTEE ON VETERANS' AFFAIRS

COMMITTEE ON SCIENCE,
SPACE, AND TECHNOLOGY

Congress of the United States
House of Representatives
Washington, DC 20515-0902

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October 17, 2017

Secretary Sonny Perdue
Department of Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250

Administrator Scott Pruitt
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20004

Commissioner Scott Gottlieb
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Secretary Perdue, Administrator Pruitt, and Commissioner Gottlieb,

Advances in agricultural biotechnology provide enormous potential to address some of society's most difficult challenges. Biotechnology and emerging technologies such as gene editing can enhance environmental stewardship, help manage pests and diseases like Zika and citrus greening, and aid in the reduction of hunger, food waste, and nutritional insufficiencies. It is vital, however, that these tools have a consistent, science-based, risk-proportionate regulatory system, and that we remove any unnecessary burdens that would inhibit the use of these innovative solutions.
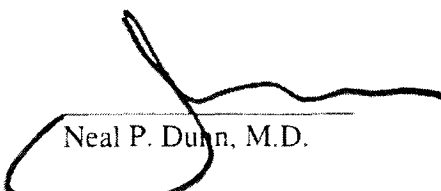
As your agencies continue to engage in the Interagency Taskforce on Agriculture and Rural Prosperity and explore other regulatory improvement opportunities, we believe there are several recent biotechnology regulatory efforts that warrant your attention. On January 19, 2017, the U.S. Department of Agriculture's (USDA) Animal Plant and Health Inspection Service (APHIS) published a draft revision to its Part 340 biotechnology regulations. The U.S. Food and Drug Administration (FDA) proposed expanding the scope of its guidance for industry (GFI) #187 to regulate any animal intentionally altered using gene editing techniques as a new animal drug. While we appreciate the thoughtful, science-based direction USDA offers on products of biotechnology and gene editing that APHIS has ample experience regulating, we are concerned that these drafts offer deeply conflicting regulatory approaches. Moreover, we do not believe they provide the consistent, appropriate system needed to promote the development of these innovative tools.

These contradictory proposals have sent inconsistent signals to our trade partners, who are in the midst of determining their own approaches to these technologies. We are concerned that if the Administration does not quickly develop a uniform position on biotechnology in agriculture, including gene editing, we will see an unworkable patchwork of international regulations emerge that will effectively further suppress American innovation and the solutions that come with it.

We urge you to coordinate with each other and stakeholders to improve these regulatory proposals in ways that are consistent and foster innovation. We also request that you increase engagement with our trading partners to promote a harmonized, science-based international regulatory system for these products. Finally, as you consider ways to engage with the public to discuss the continued advancement of biotechnology in agriculture, recall that Congress provided $3 million in FY17 for FDA and USDA for these purposes, which would aid engagement efforts.

We appreciate your work and attention to this critical issue, and stand ready to assist you in efforts to improve the regulatory climate so that our economy and society may benefit from these promising technologies.

Sincerely,

Neal P. Dunn, M.D.

K. Michael Conaway

Glenn 'GT' Thompson

Frank D. Lucas

Mike Rogers

Austin Scott
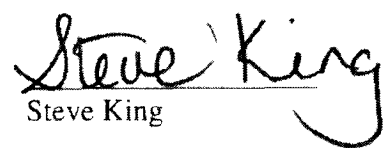
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Bob Goodlatte
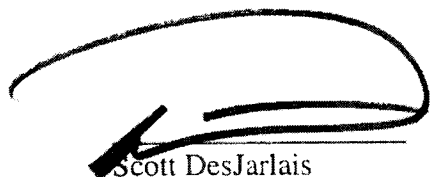
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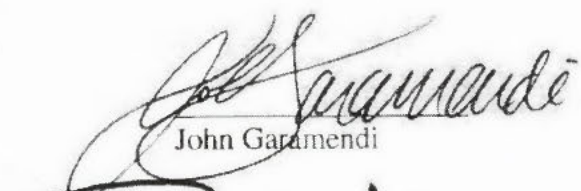
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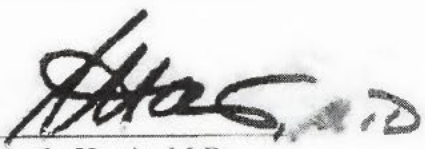
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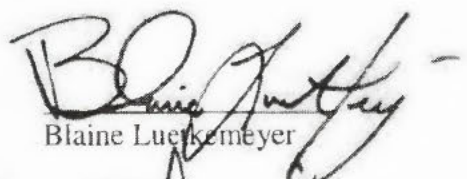
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Ron Kind
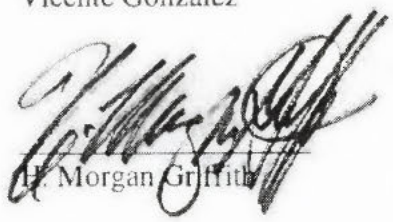
Blaine Luetkemeyer
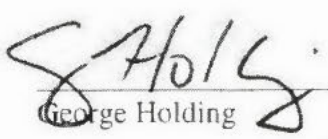
Dan Newhouse
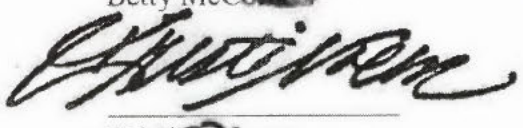
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Thomas J. Rooney

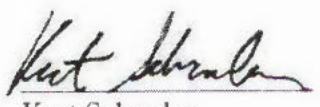Vicente Gonzalez

H. Morgan Griffith

George Holding

Lynn Jenkins
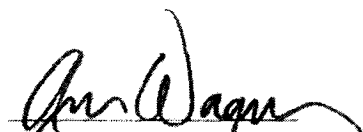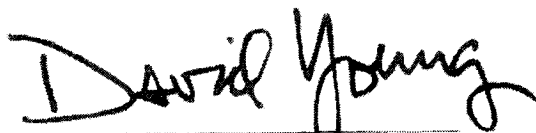
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